



HYPHEN BioMed  
155 rue d'Eragny  
95000 Neuville-sur-Oise  
France

## CERTIFICATE OF ANALYSIS

**Product Description:** ZYMUTEST Anti VIII MONOSTRIP IgG  
**Product Code:** RK039A  
**Lot No.:** FD1247  
**Expiration date:** 2026-12-26

Components	Quantity	Lot	Expiration Date
FVIII pre-coated strips	4(x8 wells)	FD1327	2026-12-26
FVIII IgG Positive Control	4 vials	FD1380	2027-01-01
Negative Control	4 vials	FD1248	2027-12-10
Anti-(h)-IgG Fc gamma HRP immunoconjugate	4 vials	FD1382	2027-01-03
Anti FVIII Sample diluent	2x12 ml	FD1437	2027-01-10
Wash solution	2x12 ml	FD0328	2027-07-26
Conjugate diluent	1x10 ml	FD0389	2027-08-02
TMB	1x10 ml	230801D02	2027-08-31
Sulfuric Acid 0,45M	1x3 ml	FD0440	2027-08-09

Analytical Data	Specification	Result
Reactivity	A450 for 175 AU/ml $\geq$ 1.10	1.11
Calibration Curve and Negative Control	Negative Control measured within acceptance range	PASS
Blank	< 0.100	0.080
Normal Plasma	M + 2 SD $\leq$ 10 AU/ml	<10 AU/ml

*This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.*

Date of Approval:

**01 AOUT 2024**

Quality Control Manager:

Claire DUNOIS  
Dir. Etudes Clin. & Val.

